

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

v.

This Document Relates To:

All cases referenced in MDL Dkt. Nos. 1471, 1472 and
Lambert, 1:13-cv-10351, Dkt Nos. 29, 30.

MDL No. 2419
Master Docket: 1:13-
md-2419-RWZ

**LIBERTY INDUSTRIES, INC.’S MOTION TO STRIKE
THE AMENDED DECLARATION OF PHILIP J. AUSTIN, PH.D.**

The Defendant, Liberty Industries, Inc. (“Liberty”), hereby moves to strike the Amended Declaration of Philip J. Austin, Ph.D. (“Amended Declaration”) filed by the PSC [Dkt. No. 1651-1]. The Amended Declaration was filed by the PSC after Liberty moved for reconsideration of this Court’s Order denying its motions for summary judgment [Dkt. No. 1619].¹ According to the PSC, the Amended Declaration is “unchanged from the original December 22, 2014 Declaration of Philip J. Austin with one exception: the amended declaration bears an updated date and the phrase ‘signed under the penalty of perjury’ above Dr. Austin’s signature.” [Dkt. No. 1651] Despite this amendment, the Amended Declaration, like the original declaration of Dr. Austin, is not admissible evidence because:

1. Dr. Austin has no personal knowledge of the conditions of the cleanrooms built by Liberty at any time before December, 2012;

¹ The Amended Declaration was filed by the PSC late and without any authority from the Court. Liberty filed its Motion for Reconsideration on December 24, 2014. The PSC filed its Opposition to that Motion for Reconsideration on January 7, 2015 [Dkt. No. 1627]. The PSC did not provide an amended declaration from Dr. Austin at that time. The Court heard oral argument on Liberty’s Motion for Reconsideration on January 14, 2015. The time to oppose Liberty’s Motion for Reconsideration has lapsed. Accordingly, the Amended Declaration is improperly before the Court and should not be considered.

2. Dr. Austin's speculation about the room in which the MPA was compounded is inadmissible without a statement of the facts supporting his speculation;

3. Dr. Austin states that Liberty knew the cleanrooms it built were to be used for sterile compounding without any basis in fact for that statement;

4. Dr. Austin makes repeated reference to his father's observations, and, therefore, it cannot be determined what Dr. Austin, as opposed to his father, observed or concluded; and

5. Dr. Austin admits that the cause of the outbreak cannot be identified, thereby undermining any reliance by the PSC on his Amended Declaration to establish causation in this matter.

I. LEGAL STANDARD

Fed. R. Civ. P. 56(c)(4) requires that a declaration used to support or oppose a motion be made on personal knowledge and set forth facts that would be admissible in evidence. Fed. R. Civ. P. 56(c)(4) provides:

An affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated.

Further, "[i]t is fundamental that '[e]xpert testimony must be predicated on facts legally sufficient to provide a basis for the expert's opinion.'" Damon v. Sun Co., Inc., 87 F.3d 1467, 1474 (1st Cir. 1996), quoting In re Salvatore, 46 B.R. 247, 253 (Bankr.D.R.I.1984). Therefore, "[a]n expert should not be permitted to give an opinion that is based on conjecture or speculation from an insufficient evidentiary foundation." Id., quoting Van Brode Group, Inc. v. Bowditch & Dewey, 36 Mass. App. Ct. 509, 520 (1994). "A district court may exclude expert testimony where it finds that the testimony has no foundation or rests on...speculative evidence." Schubert

v. Nissan Motor Corp. in U.S.A., 148 F.3d 25, 29-30 (1st Cir. 1998), quoting Casas Office Machs., Inc. v. Mita Copystar Am., Inc., 42 F.3d 668, 681 (1st Cir. 1994).

II. LEGAL ARGUMENT

A. The Amended Declaration Does Not Meet The Requirements Of Fed. R. Civ. P. 56(c)(4), And Therefore, It Must Be Stricken.

1. The Amended Declaration Is Not Based On Personal Knowledge.

The Amended Declaration does not meet the requirements of Fed. R. Civ. P. 56(c)(4) because it makes conclusory and speculative statements against Liberty as to which Dr. Austin has no personal knowledge. The Amended Declaration is based almost entirely on observations, photos, and tests taken during “the three day inspection of NECC in December 2012.” Amended Declaration, ¶3. Based on this inspection, Dr. Austin has allegedly identified defects in the cleanrooms and seeks to attribute those defects to Liberty. He states:

During our inspection of the cleanroom in December of 2012, it was observed that the ceiling system of the cleanroom was improperly designed and installed. We observed gaps between some of the light fixtures and the ceiling grid. We also observed similar large gaps between some of the HEPA filters and the ceiling grid. These light fixtures and filters should rest inside of the T shaped ceiling grid elements, with their perimeter sealing against a gasket resting on the lip of the grid elements. The weight of the lights and HEPA filters, if properly installed, should provide sufficient pressure to provide a seal that prevents contaminants from entering into the cleanroom. Amended Declaration, ¶40.

All of these alleged defects were observed in December, 2012, several years after Liberty was last on site at the NECC facility. Dr. Austin has no personal knowledge of the conditions of the cleanrooms at the time that Liberty delivered the cleanrooms to NECC and/or Ameridose; at the time that the contaminated MPA was compounded; or at any other time before December, 2012. In the absence of such personal knowledge, Dr. Austin can offer no admissible evidence tying any alleged defects observed by him to Liberty. Fed.R.Civ.P. 56(c)(4).

Further, Dr. Austin bases his opinions against Liberty on certain conclusions regarding in which cleanroom the contaminated MPA was compounded and Liberty's purported knowledge that the cleanrooms were to be used for sterile compounding. However, he provides no basis in fact for these conclusions. He states:

- “During our investigation, our observations led us to the conclusion that the contaminated MPA was most likely compounded in the main area of the 2006 cleanroom...The available information indicates that the contaminated vials of MPA were compounded in the main area of the cleanroom. As such, the discussion of the defects in the design and construction of the 2006 cleanroom is focused on this area of the cleanroom.” Amended Declaration, ¶¶34, 39.
- “As the primary contractor responsible for the finished cleanroom, Liberty Industries was responsible for ensuring that the cleanroom was properly constructed, in all aspects, to be able to provide the required cleanliness environment for compounding sterile injectable drugs.” Amended Declaration, ¶¶4, 53.

Dr. Austin provides no basis for his conclusions that the MPA was compounded in the 2006 cleanroom built by Liberty or that Liberty knew that the cleanrooms were to be used for sterile compounding. In fact, the PSC actually conceded at the status conference held on December 4, 2014 in this matter that it does not know in which room the MPA was compounded. See generally, Transcript of 12/4/14 Status Conference. Because the Amended Declaration is based on conclusory statements by Dr. Austin that lack a proper basis in fact, the Amended Declaration is not admissible and must be stricken. Fed.R.Civ.P. 56(c)(4).

2. The Amended Declaration Does Not Set Forth Facts That Would Be Admissible Evidence.

In the Amended Declaration, Dr. Austin impermissibly seeks to incorporate his father's observations and conclusions with his own, thereby rendering the Amended Declaration inadmissible. Dr. Austin makes repeated reference to “we” and “our observations” in reference to his father, Dr. Philip R. Austin, in an attempt to piggyback on his father's expertise. Dr. Philip

R. Austin has not submitted a declaration, and, therefore, his observations and conclusions are not properly before the Court. The references include:

- “In preparation of this declaration, I have considered the observations made by Dr. Philip R. Austin and me...” Amended Declaration, ¶3 [emphasis added].
- “In December of 2012, my father, Dr. Philip R. Austin, and I were retained as consultants with expertise in the area of cleanroom design and contamination control.” Amended Declaration, ¶33.
- “During our investigation, our observations led us to the conclusion that the contaminated MPA was most likely compounded in the main area of the 2006 cleanroom...” Amended Declaration, ¶34 [emphasis added].
- “During our inspection of the cleanroom in December of 2012, we identified several defects in the design and construction of the NECC cleanrooms. In particular, it was our conclusion that the most probable vector for the contamination was directly related to a defect in the design and construction of the main area of the 2006 cleanroom. Although we have been provided with additional information since our initial investigation, we still believe that the defects in the design and construction of the NECC cleanrooms played a key role in the contamination of vials of MPA.” Amended Declaration, ¶35 [emphasis added].

Based on these references, it cannot be determined what Dr. Austin, as opposed to his father, observed or concluded, rendering the Amended Declaration without a proper foundation and inadmissible. Dr. Austin cannot incorporate his father’s purported (and unsubstantiated) observations and opinions as his own.

B. The Amended Declaration Also Must Be Stricken Because Dr. Austin Has Admitted That The Cause Of The Fungal Outbreak Cannot Be Identified.

In the Amended Declaration, Dr. Austin admits that the cause of the outbreak cannot be identified, stating:

As with any biological contamination event, such as that which occurred with the contaminated vials of MPA at NECC, there are a number of possible causes...Due to the number of possible causes for contamination during the compounding process, it is unlikely that any definitive path of fungal contamination from an originating source to its final destination in the vials will be able to be identified.” Amended Declaration, ¶51 [emphasis added].

Dr. Austin's statements undermine any purported reliance by the PSC or the Court on his Amended Declaration to establish a genuine issue of material fact with respect to causation. Because Dr. Austin has admitted that the cause of the fungal meningitis outbreak cannot be identified, his Amended Declaration undermines the very conclusion that the PSC relies upon it to prove, that Liberty caused the outbreak. Accordingly, the Amended Declaration can offer no admissible evidence on the causation element of the PSC's case, and it must be stricken.

III. CONCLUSION

In sum, because Dr. Austin does not possess the requisite personal knowledge to make the statements contained in his Amended Declaration, the Amended Declaration is not admissible evidence and must be stricken. Further, in light of Dr. Austin's own admission that the cause of the subject fungal meningitis outbreak cannot be identified, his Amended Declaration can offer no admissible causation evidence against Liberty. For all of the foregoing reasons, the Amended Declaration does not provide admissible evidence against Liberty, is not proper for the Court's consideration, and must be stricken.

WHEREFORE, Liberty respectfully requests that the Court strike the Amended Declaration, and for the reasons stated in Liberty's motions for summary judgment [Dkt. Nos. 1471, 1472, Lambert Dkt. Nos. 29, 30] and its Reply, grant summary judgment in favor of Liberty.

Respectfully submitted,

LIBERTY INDUSTRIES, INC.,
By its attorneys,

/s/ Peter G. Hermes

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Dated: January 16, 2015

CERTIFICATE OF SERVICE

Pursuant to Local Rules 5.2(b)(2) and 5.4 of the Local Rules of the United States District Court for the District of Massachusetts, I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and that paper copies will be sent by first-class mail to those indicated as non-registered participants, if any, on January 16, 2015.

/s/ Peter G. Hermes

Peter G. Hermes